REMARKS

Entry of this Amendment is proper under 37 C.F.R. §1.116, because the Amendment places the application in condition for allowance for the reasons discussed herein; does not introduce any new claims; does not raise any new issue requiring further search and/or consideration because the amendments amplify issues previously discussed throughout prosecution, and places the application in better form for an appeal should an appeal be necessary.

As noted in the Office Action Summary, claims 1-20 are pending. Claims 13-16 stand withdrawn. Claims 1, 3, 8, and 18 are amended herein, and new claims 21-24 are added. Claim 1 is amended to include the subject matter of claim 4. Claim 3 is amended to recite an infectious DNA. Claim 8 is amended to depend from claim 3, and claim 18 is amended to depend from claim 2. Basis for the amendments to the claims and new claims my be found throughout the specification and claims as-filed, especially at page 2, second paragraph and lines 35-36, page 4, first paragraph and second paragraph, page 5, line 9, and page 12, second paragraph.

Thus, no new matter is presented by way of the present Amendment. Claim 4 is canceled herein. Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled herein.

Rejections Under 35 U.S.C. § 112, first paragraph

Claim 8 stands rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not purportedly enabling with regard to the biological deposit. Applicants submit herewith a Declaration, pursuant to a declaration that Applicants will *irrevocably* remove all restriction imposed on the availability to the public upon the granting of the patent. Thus, this rejection is obviated.

Claims 1, 2, 4-6, 8-12, and 17-20 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a vector comprising a full length clone of FeFV, purportedly does provide reasonable enablement for vectors containing only a portion of the genome. Claim 4 is canceled herein. With regard to the remaining claims Applicants traverse.

Claim 1 is amended herein to recite viral DNA comprising at least the 3′LTR and 5′LTR of the viral DNA. Applicants submit that it is well known in the art that the LTRs contain the sequences required for gene expression, reverse transcription and integration. Further, the specification discloses the insertion of the foreign DNA to be expressed either between the 5′LTR and the 3′LTR region or in the 3′LTR region itself, to ensure its expression (*see* present specification, page 6, lines 7 to 11). Further, the present specification further instructs the skilled artisan to replace the Gag, Pol, Env and accessory genes (*e.g.,* the *bel* genes) by the foreign DNA to obtain a replication-defective vector which is an embodiment of the invention. Accordingly, such a vector then contains the 5′LTR region, the foreign DNA and the 3′LTR region (*see* Fig. 1). Thus, the specification contains sufficient guidance for a vector as recited in the presently amended claim 1.

In addition, the specification teaches two vector types, *i.e.* replication-competent vectors and replication-defective vectors (*see* specification, paragraph overlapping pages 3 and 4). The specification further discloses how the types may be derived from a vector with the entire genome of feline foamy virus (*see* page 5, 2nd paragraph) and a method to produce that vector with the entire viral genome as their source (*see* Example 1). Thus, Applicants submit that the specification is sufficiently enabling for vectors containing the 5′LTR and the 3′LTR of a feline foamy virus.

In fact, the construction of retroviral vectors was known in the art, as acknowledged by the Office with reference to the Schmidt et al. reference(*see* last paragraph on page 6 of the Office Action). For example, the skilled artisan could use the teaching of Schmidt et al., who teach various human foamy virus vectors derived from infectious full-length human virus vector (see abstract, 1st line), to derive vectors from the full-length FeFV clone which production is disclosed in the application without any undue burden of experimentation.

In light of the above remarks and amendments to the claims made herein, Applicants request that the rejections under 35 U.S.C. § 112 be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 1-12, and 17-20 stand rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over Winkler et al. and Schmidt et al., and further in view of Coffin et al. The Office maintains that the skilled artisan would know about construction of retroviral vectors and could use the detailed information in Winkler et al. to construct FeFV vectors. The Office argues that the skilled artisan could use the sequence of FeFV disclosed in Winkler et al. to construct a vector based on FeFV.

In order to establish a case of *prima facie* obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See* M.P.E.P. 2142. Applicants respectfully submit that these criteria have not been met in the present Office Action.

The cited references, alone or in combination, fail to recite all of the elements of the presently claimed invention or to provide an expectation of success or motivation to arrive at the claimed invention.

The Office asserts that one of skill in the art could use the sequence of FeFV disclosed in Winkler to construct a vector based on FeFV. However, the Office fails to show that the cited references provide the skilled artisan with sufficient information to construct a vector starting from the information given by Winkler. Rather, the skilled artisan require a more clear disclosure in order to have a reasonable would expectation of success in making the present invention.

Winkler discloses partial clones of the FeFV which are not infectious. However, Schmidt disclose the construction of human foamy virus vectors from an infectious clone (*see* abstract, 1st line). The infectious clone is the source of all vectors taught by Schmidt et al. Thus, teaches the skilled artisan that an infectious clone is necessary to make a foamy virus vector, but fails to disclose a method for making an infectious FeFV clone from the information disclosed in Winkler. As a method for making an infectious FeFV clone is not set forth, or even suggested, there is no motivation or modify the references to arrive at the claimed FeFV vectors or expectation of success for same.

Applicants note that an infectious full-length clone is required for modifying and constructing vector derivatives, *e.g.,* replication-competent and replication-defective vectors. This fact is confirmed by Schmidt, which discloses the use an infectious full-length clone as a source for the construction of vectors (*see* page 168, Fig. 1(A)). Thus, it is not possible to just modularly combine some of the required subgenomic elements set forth by Coffin to make a retroviral vector.

Further, the method of stepwise complex molecular cloning described in Examiner 1 of the present specification had to be carefully devised and developed by the inventors to obtain an infectious clone. These steps are not derivable from the cited references.

Further, the disclosure of the full genomic viral sequence in Winkler does not lead to a retroviral vector, because the clones of the first generation containing the complete proviral DNA disclosed in Winkler et al. were not suitable as vectors. Additionally, further steps had to be applied to restore the infectiousness by exchange of env sequences until a clone efficient for experimentation was obtained (*see* page 12, 2nd paragraph).

Finally, Applicants turn specifically to claim 8 of the present invention. Claim 8 stands rejected on the assumption that the sequence of the clone is the same as that disclosed in Winkler. In response, Applicants note that the clone of claim 8 contains a recombinant viral sequence which is different from that of Winkler. The clone of the claimed sequence was obtained by replacing the segment from nucleotide positions 5980 to 10137 of clone 13, containing the viral DNA from nucleotide positions 17 to 11700 of Winkler by a corresponding PCR amplification product. This resulted in a recombinant virus having an infectiousness equal to a wild-type virus (*see* page 12, 2nd. Paragraph of the specification). Therefore, the viral DNA sequence of the plasmid pFeFV-7 claimed in claim 8 is not the same as that of Winkler.

In light of the above, Applicants request that the rejection under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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Date: July 26, 2005

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